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EPPERSON, JON D	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/077,194	**Applicant(s)** BOHN ET AL.	
	Examiner Jon D. Epperson	**Art Unit** 1639	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 04 June 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: Please see attached sheets.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

JON EPPERSON
PRIMARY EXAMINER

Advisory Action

1. Applicants' further request for reconsideration under 37 C.F.R. § 1.116 (e.g., see 6/4/07 Response, pages 1-28) was entered but found to be non-persuasive for the reasons set forth below.

Maintained Rejections and/or Objections

Claims Rejections - 35 U.S.C. 112, first paragraph

2. Claims 38, 40, 41, 42, 48 and 65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the claimed invention. This is a new matter rejection.

A. Claims 38 was amended in 2/22/05 response to recite "... administering to the patient an amount effective for the treatment of seborrheic dermatitis of a composition comprising: (A) a sole active component consisting of at least one 1-hydroxyl-2-pyridone of formula I ... in free form or as a pharmaceutically acceptable salt ... wherein the composition has a pH ranging from about 4.5 to about 6.4" in lines 3-5 and the last line of the claim. However, the Examiner cannot find support for this claim limitation with regard to the "pharmaceutically acceptable salt" embodiment. For example, Applicants' specification states, "... when using the compounds in salt form, the adjustment of the pH range mentioned has to be carried out using organic acids" (e.g., see specification, page 8, lines 30-32; see also Example 7 wherein "lactic acid" is used to adjust the pH). Furthermore, organic acids, including lactic acid, are known to possess anti microbial

action (e.g., see Lange, page 7, last paragraph, "... acids per se possess an antimicrobial action, such as fumaric acid and azelaic acid. In this way the effect of the antimycotic in phase I as well as phase II is enhanced!"; see also paragraph bridging pages 9-10, "Examples of these acids are ... lactic"). Applicants have not shown where support for this new genus of compounds that contains "1-hydroxyl-2-pyridone of formula I salt + "non-active" organic acids" can be found. If applicant believes this rejection is in error, applicant must disclose where in the specification support for this amendment can be found in accordance with MPEP 714.02. Therefore, claim 38 and all dependent claims represent new matter.

Response

3. Applicant's arguments directed to the above New Matter rejection were fully considered (and are incorporated in their entirety herein by reference) but were not deemed persuasive for the following reasons. Please note that the above rejection may been modified from it original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

[1] Applicants argue, "the Examiner himself has cited to 'facts' on the record to support Applicant's statement. In particular, on p.3 of the Final Office Action, the Examiner points to the teaching in the present specification that 'when using the compounds in salt form, the adjustment of the pH . . . has to be carried out using organic acids." However, rather than support the Examiner's position that the acid is acting as an antimicrobial, this teaching clearly describes the use of an acid solely for purposes of pH adjustment. In view of this failing alone, the Examiner

has unjustly dismissed Applicant's argument." (e.g., see 6/4/07 Response, pages 2 and 3, especially page 3, firs full paragraph).

[1] The fact that the acids may have been used to adjust the pH does not preclude their use as an antimicrobial. For example, Lange et al. state that the antimicrobial organic acids used in their phase II composition were also used to adjust the pH of the phase II composition (e.g., see Lange et al., bottom of page 9 to top of page 10).

[2] Applicants argue, "the Examiner has not demonstrated that lactic acid would be active in the treatment of seborrheic dermatitis" (e.g., see 6/4/07 Response, bottom of page 3).

[2] In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., sole active agent "in the treatment of seborrheic dermatitis") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Here, independent claim 38 states that the composition comprises "a sole active component." It does not state, as Applicants contend, that the composition comprises "a sole active component against seborrheic dermatitis." Thus, the current claims preclude the use of all other active components whether they are useful in treating seborrheic dermatitis or not. Furthermore, as noted in the previous office action, Lange expressly states that these organic acids can be used to treat seborrheic dermatitis (e.g., see 1/25/07 Final office action, page 5, section [2]).

[3] Applicants argue, "Lange teaches that when the acid is mixed with a detergent-containing solution, any alleged antimycotic effect is destroyed" (e.g., see 6/4/07 Response, pages 4 and 5, especially bottom of page 4).

[3] The Examiner respectfully disagrees. Applicants' have mischaracterized the Lange reference. Lange states that the two phase are separated because "soaps [as in phase I] are not well suited for making lower pH products [as in phase II]" (e.g., see Lange et al., page 4, second to last paragraph). Thus, there is no assertion explicit or implicit in Lange to suggest that the antimicrobial effect would be "destroyed" upon mixing. Furthermore, "[f]rom the standpoint of patent law, a compound and all its properties are inseparable." see *In re Papesch*, 315 F.2d 381, 391, 137 USPQ 43, 51 (CCPA 1963)). Thus, the addition of an organic acid would necessarily constitute the addition of antimycotic because its properties cannot be separated from the compound.

Accordingly, the New Matter rejection cited above is hereby maintained.

Claims Rejections - 35 U.S.C. 112, second paragraph

4. Claims 38-42, 48 and 61-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. For **claim 38**, the "pharmaceutically acceptable salt" embodiment requires two active ingredients, (1) the salt of a compound of formula I and (2) the organic acid that is used to adjust the pH (e.g., see specification, page 8, lines 30-32, "... when using the compounds in salt form, the adjustment of the pH range mentioned has to be carried out

using organic acids"; see also Example 7 wherein "lactic acid" is used to adjust the pH; see especially dependent claim 65 wherein "lactic acid" is specifically required by the claims, which further limits independent claim 38) and, as a result, the claim cannot be limited to a "sole" active ingredient. For example, organic acids, including lactic acid, are known to possess anti microbial action (e.g., see Lange, page 7, last paragraph, "... acids per se possess an antimicrobial action"; see also paragraph bridging pages 9-10, "Examples of these acids are ... lactic"; see especially, page 15, second set of ingredients, "lactic acid ... (bacterio and mycostatic agent)"). Thus, it is not clear how the composition comprises a "sole" active ingredients when more than one active ingredients are being claimed (e.g., formula I salt + lactic acid). Consequently, the metes and bound of the claimed invention cannot be determined. Therefore, claim 38 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

B. For **claims 38-42, 48, 53, 55-59, 61-67**, the term "seborrheic dermatitis" is vague and indefinite in view of the prosecution history. For example, Applicants state, "Dascalu et al. misuses dermatology nomenclature by confusing 'dandruff' with 'seborrheic dermatitis' ... Although seborrheic dermatitis involving the scalp may give rise to a mistaken diagnosis of dandruff, it is well understood in the field of dermatology that seborrheic dermatitis is a condition distinct from dandruff" (e.g., see 4/24/02 response, pages 19-20). Applicants define "seborrheic dermatitis" as "a disorder of the scalp which differs from simple dandruff by the presence of erythema as a sign of inflammation, by the greater degree of scaling with occasional itching and burning, and by the occurrence of eczematous changes to other body sites" (e.g., see specification,

page 1). Applicants further state, "Pityrosporum ... is assumed to be the cause of seborrheic dermatitis" (e.g., see specification, page 1, last paragraph). However, Dascalu et al. disclose a treatment for the exact same symptoms as those defined in Applicants' specification (e.g., see Dascalu et al., line 12 wherein inflammation is disclosed; see also page 5, Table 1, patient 5, wherein a high degree of scaling is disclosed; see also page 5, Table 1, patient 2 wherein a high degree of "itching" is disclosed; see also Table 5, patient 5 wherein the overall severity of the dandruff is characterized as "severe" or, in Applicants' words, not just "simple dandruff"). In addition, Dascalu et al. explicitly state that their treatment inhibits the exact yeast, Pityrosporum (e.g., see Dascalu et al., line 13; see also claim 8). Thus, it is not clear what symptoms, underlying causative agents and/or other physiochemical factors Applicants are relying on to make this distinction (i.e., there is no basis for this assertion). Thus, the metes and bound of the claimed invention cannot be determined. Therefore, claims 38-42, 48, 53, 55-59, 61-67 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

Response

5. Applicant's arguments directed to the above 35 U.S.C. 112, second paragraph rejections were fully considered (and are incorporated in their entirety herein by reference) but were not deemed persuasive for the following reasons. Please note that the above rejection has been modified from it original version to more clearly address applicants' newly amended and/or added claims and/or newly amended arguments.

[A] Applicants argue as above in the new matter rejection, "the alleged antimycotic

effect of this acid is destroyed" if the two phases are combined (e.g., see 6/4/07 Response, pages 5 and 6, especially page 6, middle paragraph

This is not found persuasive for the following reasons:

[A] Please see section [3] above for the New Matter rejection.

[B1] Applicants argue that the term "seborrheic dermatitis" is not unclear in view of the prosecution history when the evidence of record is considered as a whole, especially in view of the comments by Dr. Leaden describing the "hyperproliferation of keratinocytes" as the "hall mark" of seborrheic dermatitis, which was allegedly not described in the Dascalu et al. reference (e.g., see 6/4/07 Response, pages 8 and 9).

[B2] Applicants note that there is uncertainty in the causative agent for seborrheic dermatitis and, as a result, it "does not necessarily follow" that inhibition of Pityosporum will lead to an effective treatment for seborrheic dermatitis (e.g., see 6/4/07 Response, paragraph bridging pages 9 and 10).

[B3] Applicants state that the Janniger et al. definition for seborrheic dermatitis is incorrect (see 6/4/07 Response, paragraph bridging pages 10 and 11).

This is not found persuasive for the following reasons:

[B1] The Examiner respectfully disagrees. First, it is interesting to note that Applicants' specification never mentions this important "hallmark" (i.e., if "hyperproliferation of keratinocytes" is the "hall mark" that distinguishes seborrheic dermatitis from dandruff then why

doesn't the specification even mention it). Furthermore, the prior art indicates that hyperproliferation is also a symptom of dandruff and, as a result, could not possible be used to distinguish the Dascalu et al. reference (e.g., see Sanfilippo et al. "An Overview of Medicated Shampoos Used in Dandruff Treatment" P&T 2006, 31(7), pages 396-400, especially page 396, column 2, paragraph 3, "The pathogenesis of dandruff involves hyperproliferation"). Thus, Applicants use of the term seborrheic dermatitis in the prosecution history is still unclear. Likewise, Applicants' reference to "yellowish" scales is also common for both dandruff and seborrheic dermatitis and, in addition, is not "necessarily" a symptom of either (e.g., see International Eczeme-Psoriasis Foundation. "Actively helping Eczema & Psoriasis Sufferers". Retrieved from http://www.internationaleczema-psoriasisfoundation.org/seborrheic_dermatitis.php4 on July 8, 2007, pages 1-4, especially page 1, paragraph 1, "Seborrheic dermatitis, also known as Dandruff [i.e., both dandruff and seborrheic dermatitis display the same symptom] ... is ... characterized by loose, greasy or dry, white to yellowish scales [i.e., the scales may not be yellow]"). Thus, the yellowish scales could not be used to distinguish the Dascalu et al. reference either.

[B2] The Examiner respectfully disagrees. As previously mentioned, Dascalu et al. disclose a treatment for the exact same symptoms as those defined in Applicants' specification including page 1, lines 3-11 in addition to the presumed causative yeast, Pityrosporum (e.g., see Dascalu et al., line 13; see also claim 8). Thus, the Examiner's determination that it will treat seborrheic dermatitis is entirely reasonable. In addition, as noted previously Janniger et al. refutes Applicants' position that Seborrheic Dermatitis has a well defined meaning separate from "dandruff" stating, "In adolescents and adults, seborrheic dermatitis commonly is manifested as

'dandruff' or as an erythema of the nasolabial fold, ranging in intensity from barely perceptible to marked" (e.g., see Janniger et al., page 149, column 1, paragraph 1; see also abstract, "Seborrheic dermatitis is a common condition that usually appears as simple dandruff"). Thus, the definition in the literature is at best ambiguous as well.

[B3] First, the Examiner notes that Applicants have not provided any rationale why the Janniger et al. reference is incorrect other than to say their definition is right and the Janniger et al. reference is wrong, which is arbitrary at best. Furthermore, the Examiner sets forth another reference by WebMD, which further supports the Janniger et al. reference that seborrheic dermatitis and dandruff are the same thing (e.g., see WebhMD, "Dandruff Warning Signs, Symptoms, and Treatment on MedicineNet.com" Retrieved from http://www.medicinenet.com/seborrhea/article.htm on July 8, 2007, pages 1 of 3, especially paragraph 1, "Sebborea is also known as seborrheic dermatitis or common dandruff") (emphasis added).

Accordingly, the 35 U.S.C. 112, second paragraph rejections cited above are hereby maintained.

Claims Rejections - 35 U.S.C. 102

6. Claims 39 and 61-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Lagarde (WO 96/02226) (Date of patent is **February 1, 1996**) (translation provided) as evidenced by Wikipedia (e.g., Wikipedia, "Category: Surfactants" last modified 24 November 2005, page 1, accessed on 12/3/05 at http://en.wikipedia.org/wiki/Category:Surfactants).

For ***claims 39, 62 and 63***, Lagarde et al. (see entire document) disclose a novel

combination product comprising an anti-fungal agent selected from the 1-hydroxyl-2-pyridones such as circlpirox or octopirox and, secondly, crotamiton as an antifungal agent activity enhancer (e.g., see Lagarde et al., abstract), which anticipates the claimed invention. For example, Lagarde et al. discloses a method for treating seborrheic dermatitis in a human patient in need thereof using said combination (e.g., see page 5, middle paragraph, "Moreover, seborrheic dermatitis is more common in patients that have atopical background, cervico-cephalic atopical dermatitis, with the presence of orbicular anti-pitysrosporum specific Ig E in which the rate is highly correlated with the severity of the disease. With respect to dermatophytoses we can mention athlete's foot, scalp disease as well as all cases of onychomycosis. Given all of these pathologies, few therapies are actually effective"; see also page 6, paragraphs 3 and 4, "Therefore there is a real need for an anti-fungal product that would have different qualities ... the present invention deals with a new combination product, in which the synergistic combination offers improved anti-fungal activity"). In addition, Lagarde et al. discloses at least one 1-hydroxyl-2-pyridone of formula I as the sole active component (e.g., page 7 of the translation formula (I); see especially see page 9, first full paragraph, wherein ciclopirox (R1=cyclohexyl, R2=R4=H and R3=CH3) or octopirox (R1=2,4,4-trimethylpentyl, R2=R4=H and R3=CH3) are disclosed). Furthermore, Lagarde et al. discloses, for example, the use of a surfactant (e.g., see page 16 of the translation, last paragraph, "It is quite evident that these formulas are not limiting and that it is important to make certain of the compatibility of surface-active agents with the combination 1-hydroxy-2-pyridone /crotamiton according to the invention; see also Examples wherein surfactants like

Cocamide DEA, Cocamide MEA, Cocamidopropyl betaine are disclosed). Lagarde et al. do not state that Cocamide DEA (non-ionic), Cocamide MEA (non-ionic), Cocamidopropyl betaine (amphoteric) are "surfactants", but the Examiner contends that these would be inherent properties of these molecules as exemplified by Wikipedia (e.g., see Green People, page 1, paragraph 1, "Sodium lauryl sulphate (SLS) is an anion surfactant ... which is included as a foaming agent ... in a huge variety of commonly used products ... shampoos").

For ***claim 61***, Lagarde et al. disclose the cyclohexyl R4 group (e.g., see page 9, first full paragraph, wherein ciclopirox (R1=cyclohexyl, R2=R4=H and R3=CH3) or octopirox (R1=2,4,4-trimethylpentyl, R2=R4=H and R3=CH3) are disclosed).

For ***claim 64***, Lagarde et al. discloses at least one "additional" surfactant such as cocamidopropyl betaine + Cocamide MEA. (e.g., see Example 4).

Response

7. Applicant's arguments directed to the above 35 U.S.C. § 102 rejection were fully considered (and are incorporated in their entirety herein by reference) but were not deemed persuasive for the following reasons. Please note that the above rejection has been modified from it original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

[1] Applicants argue that Lagarde et al. cannot anticipate the claimed invention because it does not teach the use of only one active ingredient (e.g., see 6/4/07 Response, pages 12 and 13).

[1] The Examiner respectfully disagrees. As noted previously, Applicants' claims encompass more than just one active ingredient (e.g., see 35 U.S.C. § 112, second paragraph rejection above) and, as a result, Applicants' arguments are moot.

[2] Applicants reiterate that the Wikipedia reference is "unreliable" (e.g., see 6/4/07 Response, page 13, last paragraph).

[2] As noted previously, all sources of information are susceptible to mistakes. While Applicants point to potential mistakes with the Kennedy assassination, etc., no such evidence has been provided to show that the "surfactants" entry has been similarly maligned. Furthermore, Wikipedia is just as reliable as other more traditionally sources of information like Britannica. For example, the scientific journal nature, perhaps one of the most highly respected journals in the world, did a study comparing the reliability of Wikipedia to Britannica and concluded that the difference in reliability was "not particularly great" (See Study: Wikipedia as Reliable as Britannica, Get It? Online Communication and more, December 15, 2005, page 1 of 2, visited on January 21, 2007 at http://www.henrikharsbo.dk/getit/2005/12/study_wikipedia.html). If Applicants take issues with its teaching then Applicants should present references of their own to show the inconsistencies with the "surfactant" entry. This has not been done. In addition, Applicants further state that "Britannica is signed and reviewed, thereby making it much more reliable" but this assertion is not supported in fact and is not consistent with the study set forth by the prestigious journal Nature as set forth above.

Accordingly, the 35 U.S.C. § 102 rejection cited above is hereby maintained.

8. Claims 39 and 62-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Lange

(WO 88/00041) (Date of Patent is **14 January 1988**) as evidenced by Green People (Green People, "Sodium Laurel Sulphate", **2002**, page 1, accessed on 12/3/05 at http://www.greenpeople.co.uk/Organics_Features_SLS.htm) and Avre Skin Care (Avre Skin Care, "Dermatology Dictionary", **2002**, pages 1 and 10, accessed on 12/3/05 at http://www.avro.co.za/misc/about_skincare/cosmetic_ingredients.html).

For ***claims 39, 62 and 63***, Lange (see entire document) discloses a two phase cleansing, conditioning and medicinal treatment shampoo and methods of use (e.g., see Lange, abstract), which anticipates the claimed invention. For example, Lange discloses a method for treating seborrheic dermatitis in a human patient in need thereof using said shampoo (e.g., see page 12, Example 1, "Shampoo for psoriasis-like seborrhoic dermatitis"; see also page 13, paragraph 1, "The test persons were persons suffering from tenacious dandruff, while one of them suffered from a grave seborrhoeic dermatitis"; see also page 11, first full paragraph, "One may also use piroctone olamine in phase II because of its anti-seborrhoeic effect"; see also page 8, paragraphs 1 and 2, "***The phase I composition may contain anti-mycotics in the medicinal as well as the anti-dandruff variant*** ... In a specific embodiment ***one may use a water soluble anti-mycotic such as piroctone olamine (Hoechset)***, chemical name 1-hydroxyl-4-methyl-6-(2,4,4-trimethylpentyl)-2-(1H)-pyridinone"). In addition, Lange discloses at least one 1-hydroxyl-2-pyridone of formula I as the active component (e.g., see Example 2, especially page 16, paragraph 2 wherein piroctone olamine is substituted for zinc pyrithion as the sole anti-mycotic; see also page 11, first full paragraph; see also page 13, first full paragraph, "One may also [i.e., in addition to phase I] use piroctone olamine in

phase II because of its anti-seborrhoeic effect"; see also page 8, paragraphs 1 and 2, "The phase I composition may contain anti-mycotics [i.e., piroctone olamine is an anti-mycotic] in the medicinal as well as the anti-dandruff variant ... In a specific embodiment one may use a water soluble anti-mycotic such as piroctone olamine"; see also page 16, first full paragraph, "Similar or even better results were obtained when substituting piroctone olamine for zinc pyrithion [which refers to the "phase I" ingredients of Example 2 i.e., the phase II ingredient don't contain zinc pyrithion for such a substitution to occur]"; see also page 8, last paragraph). The active ingredient piroctone olamine, also known as 1-hydroxyl-4-methyl-6-(2,4,4-trimethylpentyl)-2-(1H)-pyridinone, falls within the scope of Applicants' formula (I) when R^4 = 2,4,4-trimethylpenyl (i.e., saturated hydrocarbon radical having 6 to 9 carbon atoms), R^1 = H, R^2 = methyl (i.e., alkyl having 1 to 4 carbon atoms) and R^3 = H. Furthermore, Lange discloses, for example, the use of an anion surfactant, Sodium Lauryl sulphate, in the same phase I composition (e.g., see top of page 15; see also page 16, paragraph 1 wherein piroctone olamine is "substituted" for the zinc pyrithion in that list of ingredients on the top of page 15). Lange does not state that sodium laurel sulphate is an anionic surfactant, but the Examiner contends that sodium laurel sulphate would inherently possess these properties as exemplified by Green People (e.g., see Green People, page 1, paragraph 1, "Sodium lauryl sulphate (SLS) is an anion surfactant ... which is included as a foaming agent ... in a huge variety of commonly used products ... shampoos").

For ***claim 64***, Lange discloses at least one "additional" surfactant such as lauramide DEA. Lange does not explicitly state that "lauramide DEA" is a surfactant,

but the Examiner contends that this would be an inherent property of the molecule as exemplified by Aver Skin Care (e.g., see Avre Skin Care, page 10 which discloses "lauramide DEA" as a nonionic surfactant).

Response

9. Applicant's arguments directed to the above 35 U.S.C. § 102 rejection were fully considered (and are incorporated in their entirety herein by reference) but were not deemed persuasive for the following reasons. Please note that the above rejection has been modified from it original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

Applicants argues that Lange et al. do not disclose the use of a "single" composition for the treatment of seborrheic dermatitis noting that Lange discusses the use of two phases (e.g., see 6/4/07 Response, pages 14 and 15).

The Examiner respectfully disagrees. Applicants' specification does not teach that a "single" application of a composition will "permanently" cure seborrheic dermatitis. To the contrary, multiple application of the composition must be applied (e.g., see specification, Example 8 wherein the "single" composition is reapplied throughout the week), which is consistent with the claimed method of "treating" as opposed to say a method of "curing." Thus, the claimed method of treating seborrheic dermatitis comprising the use of a single composition must not be construed to preclude the application of more than one composition later in time. Furthermore, Applicants use of "comprising" open-ended terminology (e.g., see claim 38, "A

method of treating seborrheic dermatitis ... comprising") would not preclude the use of "additional" ingredients to those "later" compositions. Here, Lange discloses the use of piroctone olamine and sodium laurel sulphate in a "single" phase I composition (e.g., see rejection above, see also section [1] with regard to the corresponding 35 U.S.C. § 102 rejection). The fact that another "different" composition is used "later in time" does not negate the fact that a "single" composition was applied first consistent with the teachings in the specification. Therefore, the phrase "administering to the patient .... a single composition" has been interpreted to mean a single composition administered at a given time, not a single composition administered for all times. Thus, Lange's phase I composition anticipates the claimed because it constitutes a "single" composition within the meaning of Applicants' claims. Consequently, the Examiner has not "dismissed" Applicants' claimed limitation but, rather, chosen to give this limitation its broadest reasonable interpretation consistent with the specification. See MPEP § 2111.

Accordingly, the 35 U.S.C. § 102 rejection cited above is hereby maintained.

Claim Rejections - 35 USC § 103

10. Claims 38-42, 48, 53-58, and 61-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lange (WO 88/00041) (Date of Patent is **14 January 1988**) and FDA (Drug Products for the Control of Dandruff, Seborrheic Dermatitis, and Psoriasis. 56 FR 63568, December 4, 1991, pages 1-3) and Dascalu et al. (WO 96/29045) (Date of Patent is **September 26, 1996**) (of record) as evidenced by Green People (Green People, "Sodium Laurel Sulphate", **2002**, page 1, accessed on 12/3/05 at

http://www.greenpeople.co.uk/Organics_Features_SLS.htm) and Avre Skin Care (Avre Skin Care, "Dermatology Dictionary", **2002**, pages 1 and 10, accessed on 12/3/05 at http://www.avro.co.za/misc/about_skincare/cosmetic_ingredients.html) and Dreumex (Dreumex, "Dreumex Liquid Soaps", no date, page 1, accessed on 12/3/05 at http://www.signus.com/dsoftsoap.htm) and Odds et al. (U.S. Patent No. 6,514,490) (Date of patent is **February 4, 2003**) and Brinkster (Brinkster, "The pH Scale", page 1, no date, accessed 12/3/05 at http://misterguch.brinkster.net/acidtutorial.html).

For ***claims 39, 41, 42, 56, 57, 62 and 63***, Lange (see entire document) discloses a two phase cleansing, conditioning and medicinal treatment shampoo and methods of use (e.g., see Lange, abstract), which anticipates the claimed invention. For example, Lange discloses a method for treating seborrheic dermatitis in a human patient in need thereof using said shampoo (e.g., see page 12, Example 1, "Shampoo for psoriasis-like seborrheic dermatitis"; see also page 13, paragraph 1, "The test persons were persons suffering from tenacious dandruff, while one of them suffered from a grave seborrheic dermatitis"; see also page 11, first full paragraph, "One may also use piroctone olamine in phase II because of its anti-seborrheic effect"; see also page 8, paragraphs 1 and 2, "***The phase I composition may contain anti-mycotics in the medicinal as well as the anti-dandruff variant*** ... In a specific embodiment ***one may use a water soluble anti-mycotic such as piroctone olamine (Hoechset)***, chemical name 1-hydroxyl-4-methyl-6-(2,4,4-trimethylpentyl)-2-(1H)-pyridinone"). In addition, Lange discloses at least one 1-hydroxyl-2-pyridone of formula I as the active component (e.g., see Example 2, especially page 16, paragraph 2 wherein piroctone olamine is substituted for zinc

pyrithion as the sole anti-mycotic; see also page 11, first full paragraph; see also page 13, first full paragraph, "One may also [i.e., in addition to phase I] use piroctone olamine in phase II because of its anti-seborrhoeic effect"; see also page 8, paragraphs 1 and 2, "The phase I composition may contain anti-mycotics [i.e., piroctone olamine is an anti-mycotic] in the medicinal as well as the anti-dandruff variant ... In a specific embodiment one may use a water soluble anti-mycotic such as piroctone olamine"; see also page 16, first full paragraph, "Similar or even better results were obtained when substituting piroctone olamine for zinc pyrithion [which refers to the "phase I" ingredients of Example 2 i.e., the phase II ingredient don't contain zinc pyrithion for such a substitution to occur]"; see also page 8, last paragraph). The active ingredient piroctone olamine, also known as 1-hydroxyl-4-methyl-6-(2,4,4-trimethylpentyl)-2-(1H)-pyridinone, falls within the scope of Applicants' formula (I) when R^4 = 2,4,4-trimethylpenyl (i.e., saturated hydrocarbon radical having 6 to 9 carbon atoms), R^1 = H, R^2 = methyl (i.e., alkyl having 1 to 4 carbon atoms) and R^3 = H. Furthermore, Lange discloses, for example, the use of an anion surfactant, Sodium Lauryl sulphate, in the same composition (e.g., see top of page 15; see also page 16, paragraph 1 wherein piroctone olamine is "substituted" for the zinc pyrithion in that list of ingredients on the top of page 15). Lange does not state that sodium laurel sulphate is an anionic surfactant, but the Examiner contends that sodium laurel sulphate would inherently possess these properties as exemplified by Green People (e.g., see Green People, page 1, paragraph 1, "Sodium lauryl sulphate (SLS) is an anion surfactant ... which is included as a foaming agent ... in a huge variety of commonly used products ... shampoos").

For ***claims 48, 58 and 64***, Lange discloses at least one "additional" surfactant such as lauramide DEA. Lange does explicitly state that "lauramide DEA" is a surfactant, but the Examiner contends that this would be an inherent property of the molecule as exemplified by Aver Skin Care (e.g., see Avre Skin Care, page 10 which discloses "lauramide DEA" as a nonionic surfactant).

The prior art teaching of Lange differ from the claimed invention as follows:

For ***claims 38, 53, 65 and 66***, Lange fails to recite the use of a pH range between about 4.5 to about 6.5. Lange only teaches a "neutral" pH (e.g., see Lange, page 6, last paragraph). Although Lange does not define the term "neutral" in terms of a numeric range, the Examiner contends that a pH range between 6-8 is generally considered to be neutral for shampoo products (e.g., see Dreumex, page 1, "Dreumex has developed three types of liquid soaps: Each has a (neutral) pH-value of 6-7; see also Odds et al., column 5, last paragraph "Some of the first active ingredients when at approximately neutral pH (pH 6 to 8)"; see also Brinkster, "Solutions with a pH between 6 and 8 are usually referred to as 'neutral' by nonscientists"). Thus, Lange teaches a pH range that overlaps in scope with the present invention (i.e., pH 6-8 overlaps in scope with a pH of about 4.5 to about 6.5). In addition, Lange teach that lowering the pH to 4-5, using organic acids like lactic acid, do not adversely affect the anti-mycotic action of the 1-hydroxyl-2-pyridones like pirocton olamine (e.g., see page 10, paragraph 2) and provide favorable bacterio and mycostatic properties on their own (e.g., see Lange, page 15, bottom).

For ***claims 40, 55 and 61***, the combined references of Lange fail to teach the use of a cyclohexyl radical.

For ***claims 53 and 54***, Lange fails to recite the use of a keratolytic agent.

However, the combined references of Dascalu et al. and FDA teach the following limitations that are deficient in Lange:

For ***claims 38, 53, 65 and 66***, in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. cir. 1990). Here, the pH range disclosed by Lange (pH 6-8 for neutral solutions) overlaps with the claimed about 4.5 to about 6.5 range disclosed by applicant and, as a result, a prima facie case of obviousness has been set forth in accordance with *In re Wertheim* and *In re Woodruff*. Similarly, a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties (e.g., see *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (Court held as proper a rejection of a claim directed to an alloy of "having 0.8% nickel, 0.3% molybdenum, up to 0.1% iron, balance titanium" as obvious over a reference disclosing alloys of 0.75% nickel, 0.25% molybdenum, balance titanium and 0.94% nickel, 0.31% molybdenum, balance titanium.). Here, Lange teaches that a pH range of 4-6 can be used in the "phase II" solution (e.g., see page 10, paragraph 2), which indicates that pirocton olamine (which is used in both "phase I" and "phase II") would continue to function as anti-mycotic even at this lower pH range. Thus, a person of skill in the art would expect pirocton olamine to have the same anti-mycotic properties whether it was at a neutral pH (6-8) or a more acidic pH (4-5). In addition, a person of

ordinary skill in the art would have been motivated to adjust the pH to 4-5 using lactic acid because of its favorable bacterio and mycostatic properties (e.g., see Lange, page 15, bottom of page).

For ***claims 40, 55 and 61***, Dascalu et al. (see entire document) teach the use of use of a cyclohexyl radical in the R^4 position (e.g., see claim 4; see also page 3, last paragraph).

For ***claims 53 and 54,*** FDA (see entire document) teaches the use of keratolytic agents like salicylic acid are suitable for topical application in the treatment of seborrheic dermatitis (e.g., see FDA, page 1, Sec. 358.701, page 2, Sec. 358.710, part (b)-(b)(4), "Active ingredients for the control of seborrheic dermatitis ... Salicylic acid, 1.8 to 3 percent").

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use keratolytic agents like salicylic acid in the medicinal treatment shampoo because the FDA explicitly approved this ingredient for its use in treating dandruff and seborrheic dermatitis. Furthermore, one of ordinary skill in the art would have been motivated to use "salicylic acid" as taught by the FDA with the medicinal treatment shampoo as taught by Lange because the FDA states that active ingredients like salicylic acid are "recognized as safe and effective" for treating seborrheic acid. Furthermore, one of ordinary skill in the art would have reasonably expected to be successful because the FDA approved the use keratolytic agents like salicylic acid for the treatment of dandruff and seborrheic dermatitis and also shows its use in conjunction with pyrithion zinc, which is explicitly disclosed as a preferred

embodiment of Lange (e.g., see Lange, Example 2; see also abstract). In addition, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to made to use ciclopiroxolamine in the seborrheic dermatitis treatment described by the combined references of Lange and FDA because Dascalu et al. explicitly states that ciclopiroxolamine is useful for this purpose (e.g., see claims 1 and 4, "A composition for treatment of seborrheic dermatitis of the scalp ... consisting of ... ciclopiroxolamines"). Furthermore, one of ordinary skill in the art would have been motivated to use ciclopiroxolamines as taught by Dascalu et al. because Dascalu et al. teach that these compounds are a "preferred' embodiment (e.g., see claim 4) . Furthermore, one of ordinary skill in the art would have reasonably expected to be successful because Dascalu et al. teach several successful examples of using anti-fungal agents like ciclopiroxolamines (e.g., see claims and examples) and, in addition, it is structurally related to the anti-fungal agents disclosed by the combined references of Lange and the FDA (e.g., 1-hydroxyl-2-pyridones are disclosed in each case).

Response

11. Applicant's arguments directed to the above 35 U.S.C. § 103(a) rejection were fully considered (and are incorporated in their entirety herein by reference) but were not deemed persuasive for the following reasons. Please note that the above rejection has been modified from it original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

[1] Applicants reiterate their position that a single composition is not disclosed in Lange

(e.g., see 6/4/07 Response, pages 16-19).

[1] The Examiner contends that this issue was adequately addressed in the Lange et al. 35 U.S.C. § 102 rejection above.

[2] Applicants argue with regard to the secondary references that Dascalu discusses dandruff, not the currently claimed seborrheic dermatitis (e.g., see 6/4/07 Response, pages 19-20).

[2] The Examiner maintains for the reasons set forth in the 35 U.S.C. § 112, second paragraph rejection above that Applicants' use of the term "seborrheic dermatitis" is unclear and inconsistent with the prior art and the prosecution history. Furthermore, the broadest reasonable interpretation (based on the prior art alone) would not preclude a definition wherein dandruff = seborrheic dermatitis especially in light of the WebMD reference, which explicitly states, "Seborrhea is also known as seborrheic dermatitis or common dandruff" (see above). Furthermore, all of the symptoms denoted by Applicants with regard to seborrheic dermatitis have also been shown to be symptoms of patients suffering from common dandruff (see above). Furthermoe, Dascalu disclose all of the symptoms set forth in Applicants' specification and, in addition, set forth what is believed to be the causative yeast (see above).

[3] Applicants again call into question the "reliability" of many of the references in the last office action (e.g., see 6/4/07 Response, page 20, paragraph 1).

[3] As noted previously, studies by some of the most respected journal (e.g., Nature) have shown these references (at least the Wikipedia reference) to be reliable. Furthermore, the

Examiner is unaware of any per se rule banning the use of internet references especially in light of the fact that Applicants have provided no sound scientific arguments that might otherwise call into question the assertions set forth therein.

[4] Applicants argue that the FDA does not even teach 1-hydroxyl-2-pyridones or a method of treating seborrheic dermatitis (e.g., see 6/4/07 Response, page 21, middle paragraph).

[4] In response to applicant's arguments against the FDA reference individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Here, the combined references teach the claimed compounds as set forth in the rejection above.

[5] Applicants repeat their "two composition" argument with regard to Lange and further note that secondary evidence such as that set forth by Kevin Kriel suggests commercial success (e.g., see pages 21 and 22, especially paragraph bridging pages 21 and 22).

[5] The Examiner contends that the "two composition" argument has been addressed at length above (see corresponding 35 U.S.C. § 102 rejection above) and that Applicants have failed to address the Examiner's previous "commensurate in scope" and "advertising" arguments in the 1/25/06 Final Office action (e.g., see Final Office action, pages 26 and 27, section [5]) and, as a result, have not overcome these previous finding of fact.

Accordingly, the 35 U.S.C. § 103(a) rejection cited above is hereby maintained.

Claims Rejections – 35 U.S.C. 102/103

12. Claims 38-42, 48 and 61-66 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Verdicchio et al. (EP0117135 A2) (Published August 19, 1984) in view of Janniger et al. (Janniger et al. "Seborrheic Dermatitis" *American Family Physician*, **July 1995**, page 149-155) and Dittmar (U.S. Patent No. 4,185,106) (Date of Patent is January 22, 1980) (of record, e.g., see 6/16/1999 FAOM, withdrawn apparently because the Dittmar reference alone did not teach the claimed pH values). Please note that a 102/103 rejection may is appropriate when the interpretation of the claim(s) is or may be in dispute, i.e., given one interpretation, a rejection under 35 U.S.C. 102 is appro-priate and given another interpretation, a rejection under 35 U.S.C. 103(a) is appropriate. See section MPEP § 706.02(m). Here the term "seborrheic dermatitis" is in dispute (see 35 U.S.C. § 112, second paragraph rejection above).

For ***claims 38 and 39***, Verdicchio et al. (see entire document) disclose a composition for treating dandruff in a human patient (e.g., see abstract and introduction; see also bottom of page 20, "Two groups of 8 people each who have dandruff are compared using each test shampoo twice weekly"). Verdicchio et al. do not explicitly state that these people have seborrheic dermatitis, but the Examiner contends that this is inherently disclosed because dandruff is a form of Seborrheic Dermatitis according to Janniger et al. (e.g., see Janniger et al., abstract, "Seborrheic dermatitis is a common condition that usually appears as simple dandruff."; see also page 149, paragraph 1, "In adolescents and adults, seborrheic dermatitis commonly is manifested as 'dandruff'"). Verdicchio et al. also disclose administering a composition comprises a sole active

component which is hydroxy pyridone such as Octopirox. Octopirox falls within the scope of Applicants' formula (I) when R^4 = 2,4,4-trimethylpentyl (i.e., saturated hydrocarbon radical having 6 to 9 carbon atoms), R^1 = H, R^2 = methyl (i.e., alkyl having 1 to 4 carbon atoms) and R^3 = H (e.g., see page 12, lines 31-34 disclosing the use of octopirox as recited in U.S. Patent No. 4,185,106; see also U.S. Patent No. 4,185,106, claim 3 wherein ethanolamine salt of 1-hydroxy-4-methyl-6-(2,4,4-trimethylpentyl)-2-pyridone (i.e., octopirox) is set forth. Verdicchio et al. also disclose the use at least one surfactant chosen from anionic surfactants cationic surfactants nonionic surfactants and amphoteric surfactants (e.g., see Verdicchio et al., page 20, Examples X and XI showing the use of cocoamido betaine, amidohydroxypropyl phosphobetaine, polyoxyethylene (80) sorbitan laurate, polyethyelen glycol (150) distearate in lines 12-24. Finally, Verdicchio et al. also disclose a pH of "about" and wherein the composition has pH ranging from about to about 4.5 to 6.5 (e.g., see Verdicchio et al., page 20, line 25 showing pH = 6.6, which is "about" 6.5).

For ***claims 40 and 61***, Verdicchio et al. disclose at least one hydroxy pyridone of formula has cyclohexyl radical in the R^4 position (e.g., see Verdicchio et al., page 12, line 32 disclosing the use of compounds set forth in Dittmar i.e., U.S. Patent No. 4,185,106; see also Dittmar, column 1, line 51).

For ***claims 41 and 62***, Verdicchio et al. disclose $CH_2CH(CH_3)CH_2C(CH_3)_3$ in the position in the R4 position (e.g., see Verdicchio et al., page 12, line 32 disclosing the use of compounds set forth in Dittmar i.e., U.S. Patent No. 4,185,106; see also Dittmar, claim 3).

For ***claims 42 and 63***, Verdicchio et al. disclose Octopirox (i.e., 1-hydroxy-4-methyl-6-(2,4,4-trimethylpenty1)-2(H)pyridine (e.g., see Verdicchio et al., page 20, line 22; see also page 12, line 32 disclosing compounds set forth in U.S. Patent No. 4,185,106; see also Dittmar, claim 3).

For ***claims 48 and 64***, Verdicchio et al. method of treating seborrheic dermatitis in human patient in need thereof as claimed in claim 38 in which the composition further comprises at least one additional surfactant chosen from anionic cationic nonionic and amphoteric (e.g., see Verdicchio et al., page 20, wherein cocoamido betaine, amidohydroxypropyl phosphobetaine, polyoxyethylene (80) sorbitan laurate, polyethyelen glycol (150) distearate are disclosed; see also page 5, last paragraph, "The amphoteric surfactants which are useful in the compositions of the present invention include betaines ... phosphobetaines").

For ***claims 65 and 66***, Verdicchio et al. disclose lactic acid to adjust the pH (Verdicchio et al., page 12, line 32 disclosing the use of compounds set forth in Dittmar i.e., U.S. Patent No. 4,185,106; see also Dittmar, column 5, line 47 disclosing the use of "lactic acid" salts).

In the alterative that dandruff is not considered to be the same thing as seborrheic dermatitis as argued by Applicants in direct contrast to the Janniger et al. reference, the claimed treatment would still be prima facie obvious to one of ordinary skill in the art because both dandruff and seborrheic dermatitis are produced by the same causative agent, Pityrosporum ovale, and is generally treated using the same types of medicinal shampoos (e.g., see Janniger et al., page 152, column 1 disclosing Piyrosporum ovale; see

also column 2, Therapy section and Table 2). Thus, even if, for the sake of argument, dandruff could be defined as a "separate" ailment apart from seborrheic dermatitis a person of skill in the art would still expect the same medicinal shampoos to be used in the treatment of both as defined by Janniger et al. Therefore, it would be prima facie obvious to treat the "separate" seborrheic dermatitis condition with a dandruff shampoo like the dandruff shampoo set forth in Verdicchio. One would have a reasonable expectation of success because both are conditions are produced from a common microbe, Pityrosporum ovale organism. In addition, Dittmar et al. explicitly state that their pyridones can be used as "anti-seborrheic agents." (e.g., see Dittmar et al., column 6, line 24). Thus, a person of skill in the art would be motivated to use the "dandruff" compositions to treat both seborrheic dermatitis as well as dandruff. Furthermore, a person of skill in the art would also have reasonably expected to be successful because all reference show the use of medicinal shampoos for the topical treatment of the scalp.

Response

13. Applicant's arguments directed to the above 35 U.S.C. § 102/103 rejection were fully considered (and are incorporated in their entirety herein by reference) but were not deemed persuasive for the following reasons. Please note that the above rejection has been modified from it original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

[1] Applicants argue that Verdicchio does not teach a method of treating seborrheic dermatitis but, rather, a method for treating dandruff, which is not the same arguing that reliance

on the Janniger reference is misplaced because Janniger improperly confuses the term "dandruff" with the term "seborrheic dermatitis" (e.g., see 6/4/07 Response, paragraph bridging pages 22 and 23).

[1] The Examiner respectfully disagrees. The term seborrheic dermatitis is unclear (e.g., see 35 U.S.C. § 112, second paragraph rejection above). Furthermore, there is no evidence that Janniger has confused the definition. To the contrary, Janniger has merely decided to use a "broader" definition than that chosen by Applicants. Furthermore, Janniger's definition is supported by numerous other references (e.g., see WebMD reference above, "Seborrhea is also known as seborrheic dermatitis or common dandruff") and the sympotoms and causative agent disclosed by Verdicchio, Lange, etc. are not inconsistent with the definition set forth in Applicants' specification (e.g., see paragraph 1) and prosecution history (e.g., see above controversy surrounding the Dascalu reference).

[2] Applicants argue that there is no reasonable expectation of success because it is unclear what causes seborrheic dermatitis (e.g., see 6/4/07 Response, pages 23 and 24).

[2] The Examiner respectfully disagrees. It is clear from the art that dandruff and seborrheic dermatitis (at least the mild forms) are almost indistinguishable. Furthermore, the best scientific data indicates that the same causative agent, P. ovale, is responsible for both. While there is no "definitive proof" on this point it would still be "reasonable" to assume that P. ovale causes both. Thus, the Examiner's interpretation of the facts is reasonable. Obviousness does not require absolute predictability. *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA

1976); In re Clinton, 527 F.2d 1226, 188 USPQ 365 (CCPA 1976).

[3] Applicants argue that anti-seborrheic dermatitis agent are not the same thing as anti-seborrheic agents stating, "[m]erely dealing with oily skin by using anti-seborrhea agents does not equal treating seborrheic dermatitis" (e.g., see 6/4/07 Response, pages 24 and 25).

[3] The Examiner respectfully disagrees. Oily skin plays a big role in seborrheic dermatitis as exemplified by the word "seborrhea" which means "too much oil." Thus, a person of ordinary skill in the art would be motivated to use agents that treat oily skin against seborrheic dermatitis whether such a treatments constituted a formalistic treatment of seborrheic dermatitis or not.

[4] Applicants argue, "Dittmar's list of further additives teaches away from a method that uses a composition in which 1-hydroxyl-2-pyridone is the sole active component of the composition. If anything, a composition with multiple active ingredients is presumably more effective than a composition with just one" (e.g., see 6/4/07, page 25, last paragraph).

[4] No such teaching away exists. The test to determine if a reference "teaches away" is to determine if one "would be discouraged from following the path set out in the reference, or would be lead in a direction divergent from the path that was taken by the applicant" *In re Gurley*, 27 F.3d at 553, 31 USPQ2d at 1131 (Fed. Cir. 1994). For example, in *In re Fine*, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988), a system for measuring minute quantities of nitrogen presumably for the detection of drugs and explosives was claimed. The claims were rejected as being obvious over Eads in view Warnick. Eads disclosed a method for separating and

identifying sulfur compounds. Warnick disclosed a process for detecting pollutants in the atmosphere by measuring the level of nitric oxide. The PTO held that it would have been *prima facie* obvious to substitute the nitric oxide detector of Warnick for the sulfur dioxide detector of Eads. On appeal, the Federal Circuit reversed noting that Eads deliberately sought to avoid the use of nitrogen because the sulfur detector was adversely affected by substantial quantities of nitrogen. Thus, according to the CAFC, "instead of suggesting that the system be used to detect nitrogen compounds, Eads deliberately seeks to avoid them; it warns against rather than teaches Fine's invention." See *Id.* at 1599. Thus, *In re Fine* provides an example of a "teaching away" by disclosing that the presence of a claimed element, nitrogen, is undesirable. No such "teaching away" exists in the present case. That is, neither Dittmar nor Verdicchio teach that the claimed method of treatment "will not work" unless multiple active ingredients are used. To the contrary, Verdicchio expressly states that multiple active ingredients are not required.

Accordingly, the 35 U.S.C. § 102/103 rejection cited above is hereby maintained.

Double Patenting

14. Claims 38-42, 48 and 61-66 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-23 and 26-29 of copending Application No. 10/606,229. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in both applications are drawn to the same treatment of seborrheic dermatitis using the same 1-hydroxyl-2-pyridone compounds having the same generic formula. Thus the applications overlap in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting

claims have not in fact been patented.

Response

15. Applicant's arguments directed to the above double patenting rejection were fully considered but were not deemed persuasive for the following reasons. Please note that the above rejection has been modified from it original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

Applicants argue, are that the DP rejection should be withdrawn because all other rejections have been overcome by Applicants' arguments and, as a result, the DP rejection is the only one left standing (e.g., see 6/4/07 Response, pages 26 and 27).

As noted previously, a double patenting rejection is NOT the only rejection remaining in one of the applications and, as a result, Applicants' arguments are moot (e.g., see 1/25/07 Final rejection, page 28, response to DP rejection).

Accordingly, the double patenting rejection cited above is hereby maintained.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.
July 9, 2007

JON EPPERSON
PRIMARY EXAMINER